

Ethylene Oxide (EtO) Commercial Sterilization

CAA Section 114 Survey

Introduction

The U.S. Environmental Protection Agency (EPA) is requesting facility data and information to inform the Technology Review project for 40 CFR Sterilization source category. The purpose of this survey is to enable facilities to submit accurate facility information. For more detailed instructions, see the Section 114 transmittal letter at: <https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities>

Instructions

This survey contains sheets and data fields shaded in different colors. As a general rule:

Sheets and fields shaded in blue indicate that reporters shall provide inputs according to the corresponding instructions
Sheets and fields shaded in gold contain instructions and supporting information that help reporters with this survey
Fields shaded in gray indicate that these either do not need to be filled out or will be automatically filled out based on reporter's inputs in relevant sections
Fields shaded in red by reporter indicate that these fields contain confidential business information (CBI), and relevant data needs special handling

** If any information you entered contains CBI, select "Yes" in the designated cell (Cell N2) in each tab throughout this survey, shade the fields accordingly, and follow the instructions specified in the Instructions Document*

This survey contains the following tabs (You may click on the tab names below to visit each individual tab):

Introduction (this tab)	Introduction and instructions for completing and submitting this survey
Terms (link)	Definitions or explanations of certain technical terms that are mentioned throughout this survey
Facility Details (link)	Information about facility registration, ownership, general characteristics, facility-level data, legal documents, etc.
Room Area (link)	Characteristics, inventory of components and control of individual room areas where EtO is used or emitted
EtO & EG Storage (link)	Questions regarding EtO storage in drums and containers, and ethylene glycol (EG) tanks
Sterilizer Chambers (link)	Operation, monitoring and control characteristics of sterilizer chambers
Aeration (link)	Details of aeration equipment
APCD Summary (link)	Information about all air pollution control devices operated by facility
APCD Details (link)	Details regarding air pollution control devices such as scrubbers, catalytic oxidizers, thermal oxidizers, etc.
EtO Monitoring (link)	Information about workspace monitoring, personal monitoring, room monitoring, etc. conducted by facility
Miscellaneous (link)	Questions regarding facility's wastewater treatment and other items of EtO commercial sterilization operations
Additional Info (link)	Use this tab if you need extra space to provide any additional information requested within this survey
Attachments (link)	Designated fields for reporter to attach documents requested throughout this survey
Certification (link)	Reporter's information and certification for completing and submitting this survey

If you need extra space to provide any additional information within this survey, use the space provided in Section M in Additional Info tab

Submitting Completed Surveys

There are two ways to submit your survey that contains no CBI information:

- (1) Save the completed survey on a CD, DVD or thumb drive, and mail it to:
U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
U.S. EPA Mailroom (E143-05)
Attn: Mr. Jonathan Witt
- (2) Email to Mr. Jonathan Witt at: Witt.Jon@epa.gov

To submit your survey that does contain CBI information, see the Instructions Document to the Section 114 transmittal letter

part 63, subpart O, Commercial
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[ilities](#) (click to visit).

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1. Definitions

Term	Definition
Accelerated aeration	Aeration conducted in a heated aeration chamber or cell, not an aeration room, combined with
Aeration cell/chamber	Any vessel that is used to facilitate off-gassing of ethylene oxide at a sterilization facility. If si
Aeration room	Any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization fac
Aeration room vent (ARV)	The point(s) through which the evacuation of ethylene oxide-laden air from an aeration room
Balancer/abator system	An air pollution control device (APCD) that consists of a combination of a water balancer and
Cascading air	Ventilation air removed from one room area or process, with a lower EtO concentration, is ve
Chamber exhaust vent (CEV)	The point(s) through which ethylene oxide-laden gas is removed from the sterilization chamb
Combination-chamber sterilizer	Any enclosed vessel in which both the sterilization process and the aeration process occur wi
Dwell period	The length of time that the product is exposed to ethylene oxide in sterilizer chamber for the
Engineering test	A test that measures the amount of pollutants being emitted, demonstrates the capture effic
Ethylene oxide (EtO) service	A piece of equipment either contains or contacts ethylene oxide as a liquid or gas at any conc
Fugitive emissions	Emissions (of ethylene oxide) which are not routed through the existing control equipment
Natural draft opening (NDO)	Any permanent opening in the enclosure that remains open during operation of the facility a
Performance test	A test that measures the amount of pollutants being emitted, demonstrates the capture effic
Research and laboratory facility	Any stationary source whose primary purpose is to conduct research and development into n
Single-item sterilizer	Any enclosed vessel in which sealed pouches containing product and ethylene oxide gas for t
Sterilization chamber vent (SCV)	The point (prior to vacuum pump) through which the evacuation of ethylene oxide from the s
Sterilization facility	Any stationary source where ethylene oxide is used in the sterilization or fumigation of mate
Sterilization operation	Any time when ethylene oxide is removed from the sterilization chamber through the steriliz
Sterilizer chamber	Any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene oxide/inert

2. Acronyms

Acronym	Term	Acronym	Term
APCD	air pollution control device	ID	identifier
ARV	Aeration room vent	in. H ₂ O	inches of water
CAA	Clean Air Act	kWh	kilowatt hour
CBI	Confidential business information	LEL	lower explosive limit
CEMS	Continuous emissions monitoring system	mg/L	milligrams per liter
CEV	Chamber exhaust vent	NAICS	North American Industrial Classific
cfm	Cubic feet per minute	NDO	natural draft opening
CFR	Code of Federal Regulations	ppmv	parts per million, volun
EG	ethylene glycol	psig	pressure per square inch, g
EIS	Emission Inventory System	QA	quality assurance
EPA	Environmental Protection Agency	QC	quality control
EtO	ethylene oxide	R&D	research and developme
ICR	information collection request	SCV	sterilization chamber ve

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A. Facility Details

Table 1. Facility Information

Field #	A-1	A-2	A-3	A-4
Data	Primary NAICS code	EIS ID	Facility name	Facility address
Instruction	Enter the primary NAICS code for the facility *	Enter EIS ID for the facility	Enter facility name	Enter the street address of facility verified by U.S. Postal Service (USPS). Do <u>not</u> include P.O. box in this field
Response	339113		Midwest Sterilization Corporation	12010 General Milton Drive

* For assistance in determining your facility's NAICS code, see the website for the North American Industry Classification System (NAICS), [mai](#)

Table 2. Parent Company Information

Field #	A-13	A-14	A-15	A-16
Data	Parent company	Parent company address	Parent company city	Parent company state
Instruction	Enter parent company name	Enter the street address of parent company verified by U.S. Postal Service (USPS). Do <u>not</u> include P.O. box in this field	Enter parent company city	Select from the dropdown menu in this column
Response	Midwest Sterilization Corporation	1204 Lenco Avenue	Jackson	MO

* To determine the employee threshold for a small business, you may look up the small business size standard using six-digit NAICS codes. The §121.201, "What size standards has SBA identified by North American Industry Classification System codes?", table "Small Business Size Standards" Website for the Small Business Administration: <https://www.sba.gov/>. (click to visit) Code of Federal Regulations (CFR), part 121: <https://www.ecfr.gov/cgi-bin/text-idx?SID=85df5b1185a8b127a9b324c6583f72c6&mc=true&nc>

Table 3. Facility Documents

Field #	A-21	A-22	A-23
Data	Facility diagrams	Process flow diagrams	Most recent air permit(s)
Instruction	Provide diagrams of your facility	Provide process flow diagrams of the	Provide the most recent air permit(s)
Response	Attach all requested documents in the	Attach all requested documents in	Attach all requested documents in the

Table 4. Facility Buildings

Field #	A-26	A-27	A-28	A-29
Data	Building ID	Building height	Building corner 1	Building corner 2
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each building	Enter the (average) height of the building (feet)	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point
Response				

Does any of the information you entered in this tab contain confidential business information (CBI)? Select from the options in Cell N2 on the right →
If yes, be sure to *shade the fields containing CBI in red*, and follow the instructions specified in the Instructions Document

Yes

A-5	A-6	A-7	A-8	A-9	
Facility city	Facility state	Facility zip code	Phone number	Number of employees at facility	Operating status in current year
Enter facility city	Select from the dropdown menu in this column	Enter facility zip code verified by U.S. Postal Service (USPS)	Provide a contact phone number at the facility	Select from the dropdown menu in this column. Full-time, part-time, and temporary employees should be counted equally	Select from the dropdown menu in this column
Laredo	TX	78045	(956)726-9175	101-250	Operating

maintained by the U.S. Census Bureau: <https://www.census.gov/eos/www/naics/>. (click to visit)

A-17	A-18	A-19	A-20
Parent company zip code	Phone number	Is parent company a small business?	Number of employees at parent company
Enter parent company zip code verified by U.S. Postal Service (USPS)	Provide a contact phone number at the parent company	Select from the dropdown menu in this column. For more instructions, see the footnote below this table	Select from the dropdown menu in this column
63755	(573) 243-8456	Yes	≤ 250

Size standards used to define Small Businesses are provided in 13 CFR 121, Small Business Size Regulations. See standards by NAICS Industry, column "Size standards in number of employees".

[code=pt13.1.121&rgn=div5](#). (click to visit)

A-24	A-25
Application documents for the most	Startup, shutdown and malfunction
Provide the application documents for	Provide the startup, shutdown and
Attach all requested documents in the	Attach all requested documents in the

A-30	A-31	A-32	A-33
Building corner 3	Building corner 4 (if any)	Building corner 5 (if any)	Building corner 6 (if any)
Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point

A-10	A-11		A-12	
Comments	Operating hours		Is there a plan to expand/modify/close this facility in the near future?	
If you choose an option other than "operating" in the previous column, please add a brief comment in this column	Enter the <u>daily</u> operating hours on average of the facility (hours)	Enter the <u>annual</u> operating hours on average of the facility (hours)	Select from the dropdown menu in this column	Provide a short explanation if you select "Yes" on the left
	24.00	8760.00	No (skip to A-13)	

A-33	A-34		A-35
Building corner 6 (if any)	Building corner 7 (if any)		Additional comments
Enter the longitude of this building corner. Specify to the <u>6th</u> decimal point	Enter the latitude of this building corner. Specify to the <u>6th</u> decimal point	Enter the longitude of this building corner. Specify to the <u>6th</u> decimal point	Enter any additional comments that you may have regarding the information provided in this table about buildings and building corners

Response	Warehouse	25.00	27.620473	-99.505343	27.619318	-99.504648
	Safe Cell	20.00	27.620734	-99.504746	27.620547	-99.504679

Table 5. Facility-level Data

Field #	A-36		A-37	A-38
Data	EtO usage at your facility for the last 5		Materials sterilized at your facility	Percentage of total materials sterilized
Instruction	Enter <u>calendar year</u> in this column	Enter the corresponding <u>EtO usage</u> in this column (<u>pounds</u>)	List one type of material in each cell	Provide the approximate percentage of total materials sterilized with EtO based on <u>volume of material throughput</u>
Response	2019	1,288,931.00	Medical products	100.00%
	2018	1,144,226.00	Medical products	
	2017	1,122,232.00	Medical products	
	2016	1,112,723.00	Medical products	
	2015	961,420.00	Medical products	

[illegible]

A-39	A-40		A-41		A-42
Percentage of total materials sterilized	Annual EtO stack emissions of facility		Annual EtO fugitive emissions of		Documentation
Provide the approximate percentage of total materials sterilized with EtO based on <u>dollar amount</u>	Enter <u>calendar year</u> in this column	Enter the <u>value</u> of annual EtO emissions in this column (pounds)	Enter <u>calendar year</u> in this column	Enter the <u>value</u> of annual EtO emissions in this column (pounds)	Provide calculations documentation for EtO and fugitive emission factors use annual EtO emission
100.00%	2019	16,293.00	2019	541.00	Attach all requested documentation "Attachment 1"
	2018	14,631.00	2018	481.00	
	2017	14,374.00	2017	471.00	
	2016	14,264.00	2016	467.00	
	2015	17,362.00	2015	413.00	

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B. Individual Room Area (All Areas where EtO is Used or Emitted)

Table 1. Characteristics of Room Areas

Field #	B-1	B-2	B-3
Data	Room area ID for all rooms and areas where EtO is used or emitted	Category of the room area	Activities conducted in the room
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each room	Select from the dropdown menu in this column	Provide a brief explanation of the activities in each room
Response	EO Room	EtO storage	Stores and distributes ethylene oxide
	Chamber 1	Sterilizer room area	Sterilization chamber sterilizes product
	Chamber 2	Sterilizer room area	Sterilization chamber sterilizes product
	Chamber 3	Sterilizer room area	Sterilization chamber sterilizes product
	Chamber 4	Sterilizer room area	Sterilization chamber sterilizes product
	Chamber 5	Sterilizer room area	Sterilization chamber sterilizes product
	Chamber 6	Sterilizer room area	Sterilization chamber sterilizes product
	Chamber 7	Sterilizer room area	Sterilization chamber sterilizes product
	Chamber 8	Sterilizer room area	Sterilization chamber sterilizes product
	Chamber 9	Sterilizer room area	Sterilization chamber sterilizes product
	Chamber 10	Sterilizer room area	Sterilization chamber sterilizes product
	Vacuum Pump Room	Other (sterilizer vacuum pump area)	Some sterilizer vacuum pumps are located here
	Warehouse	Shipping or warehouse	Storage of sterilized product
	Emissions Room	APCD room	Contains the wet scrubber system
	Safe Cell	APCD room	Contains the safe cell system

Table 2. Natural Draft Openings (NDO)

Field #	B-1	
Data	Room area ID for all rooms and areas where EtO is used or emitted	Natural draft openings

Does any of the information you entered in this tab contain confidential business information (CBI)? Select from the options in Cell N2 on the right →
If yes, be sure to *shade the fields containing CBI in red*, and follow the instructions specified in the Instructions Document

No

Room area	B-4 Floor area	B-5 Room height	B-6 Temperature			B-7 Relative humidity
Tests conducted in	(square feet)	(feet)	Enter temperature set point or range for summer in this column (Fahrenheit)	Enter temperature set point or range for winter in this column (Fahrenheit)	Enter temperature set point or range for intermediate seasons in this column (Fahrenheit)	Enter average or range of relative humidity (percent)
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
	1062.00	21.50	95.00	74.00	84.50	33.00%
done here	1121.00	21.50	95.00	74.00	84.50	33.00%
	143500.00	25.00	95.00	74.00	84.50	33.00%
	1711.00	41.50	95.00	74.00	84.50	33.00%
	4200.00	20.00	95.00	74.00	84.50	33.00%

B-12	
Drift opening (NDO) 1 (if any)	

B-8 Pressure drop		B-9 Air flow (ventilation)	B-10 Air flow (conditioned)	B-11 Number of air changes per hour
Enter the pressure drop across room area (inch H2O)	Specify definition of pressure drop, or locations based on which pressure drop is measured (e.g., farthest point to control device inlet)	Enter average or range of ventilation air flow (actual cubic feet per minute, acfm)	Enter average or range of conditioned air flow (actual cubic feet per minute, acfm)	Enter average or range of number of air changes per hour
		6222		8.7
		2077		7.7
		2163		8.0
		1992		7.4
		2425		9.0
		1992		7.4
		2395		8.9
		1992		7.4
		1992		7.4
		2554		9.4
		3083		11.4
		15000		97.9
		12393		7.7
		1200		20.7
		10400		8.2

B-13
Natural draft opening (NDO) 2 (if any)

B-14		
Natural draft opening (NDO) 3 (if any)		

	B-15
	Natural draft opening (NDO)

4 (if any)	

B-16	
Natural draft opening (NDO) 5 (if any)	

B-17

Natural draft opening (NDO) 6 (if any)

	B-18
	Natural draft opening (NDO) 7 (if any)

	Natural draft o

B-19	
opening (NDO) 8 (if any)	

B-20

Natural draft opening (NDO) 9 (if any)

B-21

Natural draft opening (NDO) 10 (if any)



Instruction	This column will be auto-populated based on your entries in the previous fields	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point
Response	EO Room	EO-BD-1	Window	Vertical	27.620865
	Chamber 1	CH1-BD-1	Window	Vertical	27.620618
	Chamber 2	CH2-BD-1	Window	Vertical	27.620538
	Chamber 3	CH3-BD-1	Window	Vertical	27.620629
	Chamber 4	CH4-BD-1	Window	Vertical	27.620490
	Chamber 5	CH5-BD-1	Window	Vertical	27.620629
	Chamber 6	CH6-BD-1	Window	Vertical	27.620741
	Chamber 7	CH7-BD-1	Window	Vertical	27.620756
	Chamber 8	CH8-BD-1	Window	Vertical	27.620788
	Chamber 9	CH9-BD-1	Window	Vertical	27.620811
	Chamber 10	CH10-BD-1	Window	Vertical	27.620640
	Vacuum Pump Room	VP-BD-1	Window	Vertical	27.620850
	Warehouse	WH-GH-1	Window	Horizontal	27.620316
	Emissions Room	EM-BD-1	Window	Vertical	27.620758
	Safe Cell	SC-ND-1	Window	Vertical	27.620689

Table 3. Leak Checks of Components in EtO Service

If leak checks are performed on multiple types of components in a room area, repeat your entries in Fields B-1 and B-22 of t

Field #	B-1	B-22	B-23	B-24	B-25
Data	Room area ID for all rooms and areas where EtO is used or emitted	Are leak checks performed in the room area?	Component type	Total component count	What is the percentage of components that are included in regular leak checks?

Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column
-99.503747	5.33	16.00	No (skip the next column)	56.25		
-99.503950	5.33	16.00	No (skip the next column)	56.25	CH1-ND-1	Door
-99.503889	5.33	16.00	No (skip the next column)	56.25	CH2-ND-1	Door
-99.503907	5.33	16.00	No (skip the next column)	56.25	CH3-ND-1	Door
-99.503871	5.33	16.00	No (skip the next column)	56.25	CH4-ND-1	Door
-99.503881	5.33	16.00	No (skip the next column)	56.25	CH5-ND-1	Door
-99.503869	5.33	16.00	No (skip the next column)	56.25	CH6-ND-1	Door
-99.503830	5.33	16.00	No (skip the next column)	56.25	CH7-ND-1	Door
-99.503882	5.33	16.00	No (skip the next column)	56.25	CH8-ND-1	Door
-99.503932	5.33	16.00	No (skip the next column)	56.25	CH9-ND-1	Door
-99.505175	5.33	16.00	No (skip the next column)	56.25	CH10-ND-1	Door
-99.503845	5.33	16.00	No (skip the next column)	56.25		
-99.504309	12.00	23.00	No (skip the next column)	25.00		
-99.503884	5.33	16.00	No (skip the next column)	56.25	EM-BD-2	Window
-99.504245	16.00	3.67	No (skip the next column)	286.00		

is table, then enter corresponding data for each component type

B-26	B-27	B-28
Frequency of leak checks	Average length of time to perform leak checks	Instrument and standard method for leak checks

Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity (feet/minute)
					No (skip the next column)	
Vertical	27.620543	-99.503926	144.00	21.50	No (skip the next column)	8.33
Vertical	27.620527	-99.503938	144.00	21.50	No (skip the next column)	8.33
Vertical	27.620613	-99.503944	144.00	21.50	No (skip the next column)	8.33
Vertical	27.620538	-99.503913	144.00	21.50	No (skip the next column)	8.33
Vertical	27.620597	-99.503920	144.00	21.50	No (skip the next column)	8.33
Vertical	27.620903	-99.503864	144.00	21.50	No (skip the next column)	8.33
Vertical	27.620843	-99.503811	144.00	21.50	No (skip the next column)	8.33
Vertical	27.620783	-99.503862	144.00	21.50	No (skip the next column)	8.33
Vertical	27.620768	-99.503849	144.00	21.50	No (skip the next column)	8.33
Vertical	27.620806	-99.503891	144.00	21.50	No (skip the next column)	8.33
Vertical	27.620308	-99.503896	5.33	16.00	No (skip the next column)	56.25
					No (skip the next column)	

B-29	B-30	B-31
Leak check procedure	Average cost per inspection	Average percentage of leaking components identified

[illegible]

B-32	B-33
Definition of leak	Applicable state/local regulations

[illegible]

	B-34	B-35
	Repair method/procedure for the leaks identified	Average cost per repair for leaks identified

[illegible]

B-36	B-37
Are there any specialty components that are not readily available on site and that need to be ordered in the event of a component replacement?	Are there any other impediments that would prevent immediate repair of leaks?

[illegible]

Table 4. Room Area Controls

Field #	B-1	B-38	B-
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B-59

B-60

B-61

Data	Room area ID for all rooms and areas where EtO is used or emitted	Is air from the room area vented to an APCD, used as cascading air, vented to the atmosphere, or handled in any other ways?	APCD 1 for	
Instruction	This column will be auto-populated based on your entries in the previous fields	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column. If you select "Other (specify)", be sure to specify between the parent
Response	EO Room			
	Chamber 1			
	Chamber 2			
	Chamber 3			
	Chamber 4			
	Chamber 5			
	Chamber 6			
	Chamber 7			
	Chamber 8			
	Chamber 9			
	Chamber 10			
	Vacuum Pump Room			
	Warehouse			
	Emissions Room			
	Safe Cell			

[illegible]

Other handling of air from room area

Provide a brief description of any air pollution control or handling procedure if air from this room area is not: vented to an APCD; used as cascading air; or vented to the atmosphere

[illegible]

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C. EtO Drum and Container Storage

Field #	Data	Instruction	
C-1	How many EtO drums and/or containers are typically stored at the facility at once?		75
C-2	Permitted amount of EtO storage	(pounds)	34,000.00
C-3	Is there a designated area for storing EtO drums	Select from the dropdown menu	Yes
C-4	Describe the designated area for EtO drum and/or		EtO drums are store
C-5	Describe the storage location for full and empty		Indoors in an enclos
C-6	Specify the maximum number of full EtO storage		seventy-five 400-po
C-7	Is the ambient air in the storage areas continually	Select from the dropdown menu	Yes
C-8	Describe the make/model and range of the		Air samples are take
C-9	How often are new drums or containers delivered to		Weekly
C-10	What is the procedure for checking drums or		Employees will verif
C-11	Are drums or containers placed next to sterilizer	Select from the dropdown menu	No
C-12	Describe how EtO is charged to the sterilizer chamber		When cycle paramet

D. Ethylene Glycol (EG) Tanks

[illegible]

Response
d in a separate storage room
ed room
and drums
n approximately every 45 minutes with a gas chromatograph. Baseline MOCON Inc. Series 8900 gas
y the Certificate of Analysis is 99.9% EtO. The employee will initial and date the certificate to indicate approval. If
ers call for ETO injection an automated control valve is opened to allow the gas to flow from the process storage

[illegible]

D-11 APCD 1 for EG tank			D-12 APCD 2 for EG tank (if any)	
APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column <u>If you select "Other (double click to specify)", be sure to type your entries between the parentheses "()"</u>	Enter the <u>average</u> air flow routed from the tank to this APCD (actual cubic feet per minute, acfm)	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column <u>If you select "Other (double click to specify)", be sure to type your entries between the parentheses "()"</u>

[illegible]

[illegible]

[illegible]

30
ordinates (d EG tank only)
Enter the longitude of stack. Specify to the <u>6th</u> decimal point
-99.503974

Ethylene Oxide (EtO) Commercial Sterilization CAA Section 114 Survey

[Click here to return to Introduction tab](#)
[Click here to visit Terms tab](#)
[Click here to visit Additional Info tab](#)

E. Sterilization Chambers

Table 1. Summary for Sterilizer Chambers

Field #	Data	Response
E-0	Enter the total number of sterilizer chambers at your facility	10

Table 2. Sterilizer Chamber Operation and Monitoring Characteristics

Field #	E-1	E-2	E-3	E-4	E-5	E-6
Data	Sterilizer unit ID	Associated EIS release point ID	Is this an R&D chamber (under the definition of research and laboratory facility)?	Does aeration of the sterilized product occur in the same sterilizer chamber?	Is this a single-item chamber?	Volume of sterilizer chamber
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each sterilizer	Enter the EIS release point ID associated with the sterilizer unit, if any	Select from the dropdown menu in this column	Select from the dropdown menu in this column (If you select "Yes" for any sterilizer, fill out Table 3 in Aeration tab)	Select from the dropdown menu in this column	(cubic feet)
Response	Chamber 1		No	No	No	4425.00
	Chamber 2		No	No	No	4425.00
	Chamber 3		No	No	No	4425.00
	Chamber 4		No	No	No	4425.00
	Chamber 5		No	No	No	4425.00
	Chamber 6		No	No	No	4425.00
	Chamber 7		No	No	No	4425.00
	Chamber 8		No	No	No	4425.00
	Chamber 9		No	No	No	4425.00
	Chamber 10		No	No	No	4425.00

Does any of the information you entered in this tab contain confidential business information (CBI)? Select from the options in Cell N2 on the right →
If yes, be sure to *shade the fields containing CBI in red*, and follow the instructions specified in the Instructions Document

Yes

E-7	E-8			E-9		
How many cycles per year are conducted in the sterilizer chamber in total?	Temperature (For combination sterilizers, enter temperature for sterilization mode only)			Relative humidity		
	Enter the <u>average</u> temperature of sterilizer chamber when in operation (Fahrenheit)	Enter the <u>maximum</u> temperature of sterilizer chamber when in operation (Fahrenheit)	Enter the <u>minimum</u> temperature of sterilizer chamber when in operation (Fahrenheit)	Enter the <u>average</u> relative humidity within sterilizer chamber when in operation (percent)	Enter the <u>maximum</u> relative humidity within sterilizer chamber when in operation (percent)	Enter the <u>minimum</u> relative humidity within sterilizer chamber when in operation (percent)
	120.00	135.00	105.00	60.00%	90.00%	30.00%
	120.00	135.00	105.00	60.00%	90.00%	30.00%
	120.00	135.00	105.00	60.00%	90.00%	30.00%
	120.00	135.00	105.00	60.00%	90.00%	30.00%
	120.00	135.00	105.00	60.00%	90.00%	30.00%
	120.00	135.00	105.00	60.00%	90.00%	30.00%
	120.00	135.00	105.00	60.00%	90.00%	30.00%
	120.00	135.00	105.00	60.00%	90.00%	30.00%
	120.00	135.00	105.00	60.00%	90.00%	30.00%

E-10 Pressure		E-11 Does the sterilizer chamber have positive pressure cycles?	E-12 EtO dose per cycle			Number
Enter the <u>average</u> pressure within the chamber during EtO dwell period (psig)	Enter the <u>magnitude of</u> <u>vacuum on average</u> that is applied during evacuation (psig)	Select from the dropdown menu in this column	Enter the <u>average</u> EtO dose per cycle (mg/L)	Enter the <u>maximum</u> EtO dose per cycle (mg/L)	Enter the <u>minimum</u> EtO dose per cycle (mg/L)	Enter the <u>average</u> number of nitrogen washes per cycle
-3.13	4.67	No				4
-3.13	4.67	No				4
-3.13	4.67	No				4
-3.13	4.67	No				4
-3.13	4.67	No				4
-3.13	4.67	No				4
-3.13	4.67	No				4
-3.13	4.67	No				4
-3.13	4.67	No				4
-3.13	4.67	No				4
-3.13	4.67	No				4

E-13		E-14			E-15	
of nitrogen washes per cycle		Nitrogen used for washes during each cycle			Annual cost of nitrogen washes	
Enter the <u>maximum</u> number of nitrogen washes per cycle	Enter the <u>minimum</u> number of nitrogen washes per cycle	Enter the <u>average</u> amount of nitrogen used during each cycle (pounds)	Enter the <u>maximum</u> amount of nitrogen used during each cycle (pounds)	Enter the <u>minimum</u> amount of nitrogen used during each cycle (pounds)	Enter the dollar amount in this column	Specify the dollar year in this column
5	3	831.00	900.00	700.00		
5	3	831.00	900.00	700.00		
5	3	831.00	900.00	700.00		
5	3	831.00	900.00	700.00		
5	3	831.00	900.00	700.00		
5	3	831.00	900.00	700.00		
5	3	831.00	900.00	700.00		
5	3	831.00	900.00	700.00		
5	3	831.00	900.00	700.00		
5	3	831.00	900.00	700.00		
5	3	831.00	900.00	700.00		

E-16			E-17			E-18
Number of air washes per cycle			Air used for washes during each cycle			Annual cost of air
Enter the <u>average</u> number of air washes per cycle	Enter the <u>maximum</u> number of air washes per cycle	Enter the <u>minimum</u> number of air washes per cycle	Enter the <u>average</u> amount of air used during each cycle (pounds)	Enter the <u>maximum</u> amount of air used during each cycle (pounds)	Enter the <u>minimum</u> amount of air used during each cycle (pounds)	Enter the dollar amount in this column
12	12	1	1,880.00	1,700.00	2,050.00	
12	12	1	1,880.00	1,700.00	2,050.00	
12	12	1	1,880.00	1,700.00	2,050.00	
12	12	1	1,880.00	1,700.00	2,050.00	
12	12	1	1,880.00	1,700.00	2,050.00	
12	12	1	1,880.00	1,700.00	2,050.00	
12	12	1	1,880.00	1,700.00	2,050.00	
12	12	1	1,880.00	1,700.00	2,050.00	
12	12	1	1,880.00	1,700.00	2,050.00	
12	12	1	1,880.00	1,700.00	2,050.00	

8	E-19	E-20		E-21	E-22
of air washes	Average electricity used per gas wash (nitrogen washes and air washes combined)	Annual cost of electricity for gas washes (nitrogen washes and air washes combined)		Are leak checks performed on sterilizer chamber?	Frequency of leak checks for sterilizer chamber
Specify the dollar year in this column	(kWh)	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	Specify the frequency of leak checks for sterilizer chamber
				Yes	1 leak test during each routine cycle (approximately 2 routine cycles ran per
				Yes	1 leak test during each routine cycle
				Yes	1 leak test during each routine cycle
				Yes	1 leak test during each routine cycle (approxiatmetly 2 routine cycles ran
				Yes	1 leak test during each routine cycle (approxiatmetly 2 routine cycles ran
				Yes	1 leak test during each routine cycle (approxiatmetly 2 routine cycles ran
				Yes	1 leak test during each routine cycle (approxiatmetly 2 routine cycles ran
				Yes	1 leak test during each routine cycle (approxiatmetly 2 routine cycles ran
				Yes	1 leak test during each routine cycle (approxiatmetly 2 routine cycles ran

E-23	E-24	E-25	
Average length of time to perform a leak check	Leak check procedure(s) for sterilizer chamber	Annual cost of leak checks for sterilizer chamber	
Enter average length of time to perform a leak check (minutes)	Provide a brief description of the leak check procedure(s) for sterilizer chamber	Enter the dollar amount in this column	Specify the dollar year in this column
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks were incurred air would leak into the chamber and nothing would leak out.		
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks		
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks		
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks were incurred air would leak into the chamber and nothing would leak out.		
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks were incurred air would leak into the chamber and nothing would leak out.		
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks were incurred air would leak into the chamber and nothing would leak out.		
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks were incurred air would leak into the chamber and nothing would leak out.		
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks were incurred air would leak into the chamber and nothing would leak out.		
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks were incurred air would leak into the chamber and nothing would leak out.		
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks were incurred air would leak into the chamber and nothing would leak out.		
300.00	Please note all routine production cycles are ran under a vacuum so if any leaks were incurred air would leak into the chamber and nothing would leak out.		

E-26	E-27	E-28	
Average quantity of leaks identified per year	Repair method/procedure for the leaks identified	Average cost per repair for the leaks identified	
Enter average quantity of leaks found per year	Provide a brief description of the repair method/procedure for the leaks identified	Enter the dollar amount in this column	Specify the dollar year in this column
	If chamber leaks are identified the sterilization software will notify the operator who will notify the maintenance department. Each leak will be		
	If chamber leaks are identified the sterilization software will notify the		
	If chamber leaks are identified the sterilization software will notify the		
	If chamber leaks are identified the sterilization software will notify the operator who will notify the maintenance department. Each leak will be		
	If chamber leaks are identified the sterilization software will notify the operator who will notify the maintenance department. Each leak will be		
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	If chamber leaks are identified the sterilization software will notify the operator who will notify the maintenance department. Each leak will be		
	If chamber leaks are identified the sterilization software will notify the operator who will notify the maintenance department. Each leak will be		
	If chamber leaks are identified the sterilization software will notify the operator who will notify the maintenance department. Each leak will be		

E-29	E-30			
Is an EtO concentration monitor used within this sterilizer chamber?	Description of the EtO concentration monitor used within this sterilizer chamber			
Select from the dropdown menu in this column	Enter the <u>type</u> of EtO concentration monitor	Enter the <u>manufacturer</u> of EtO concentration monitor	Enter the <u>model</u> of EtO concentration monitor	Specify the <u>method of detection</u> of EtO concentration monitor
Yes	optical gas detector	Sensor Electronics	1420597	Infrared
Yes	optical gas detector	Sensor Electronics	1420597	Infrared
Yes	optical gas detector	Sensor Electronics	1420597	Infrared
Yes	optical gas detector	Sensor Electronics	1420597	Infrared
Yes	optical gas detector	Sensor Electronics	1420597	Infrared
Yes	optical gas detector	Sensor Electronics	1420597	Infrared
Yes	optical gas detector	Sensor Electronics	1420597	Infrared
Yes	optical gas detector	Sensor Electronics	1420597	Infrared
Yes	optical gas detector	Sensor Electronics	1420597	Infrared

		E-31	E-32	E-33		E-34
Number		Year in which the EtO concentration monitor was installed	Expected lifetime of the EtO concentration monitor	Capital cost of the EtO concentration monitor used within this sterilizer chamber		Installation cost of the EtO concentration monitor used within this sterilizer chamber
Enter the <u>value</u> of detection level of EtO concentration monitor	Specify the <u>unit</u> of detection level of EtO concentration monitor	Enter the calendar year	Enter the expected lifetime of the EtO concentration monitor (years)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column
10.00	Mg/L	2018	2.00			
10.00	Mg/L	2018	2.00			
10.00	Mg/L	2018	2.00			
10.00	Mg/L	2018	2.00			
10.00	Mg/L	2018	2.00			
10.00	Mg/L	2018	2.00			
10.00	Mg/L	2018	2.00			
10.00	Mg/L	2018	2.00			
10.00	Mg/L	2018	2.00			
10.00	Mg/L	2018	2.00			
10.00	Mg/L	2018	2.00			

	E-35		E-36
Cost of the EtO concentration monitor used within this chamber	Annual cost of the EtO concentration monitor used within this sterilizer chamber		Standards or work practices followed for the EtO concentration monitor used within this sterilizer chamber
Specify the dollar <u>year</u> in this column	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	Provide a brief description of any standards or work practices followed for the EtO concentration monitor used within the chamber
			The ETO concentration monitor is used to measure gas concentrations during processing. These gas levels are used to verify customer
			The ETO concentration monitor is used to measure gas concentrations
			The ETO concentration monitor is used to measure gas concentrations
			The ETO concentration monitor is used to measure gas concentrations during processing. These gas levels are used to verify customer
			The ETO concentration monitor is used to measure gas concentrations during processing. These gas levels are used to verify customer
			The ETO concentration monitor is used to measure gas concentrations during processing. These gas levels are used to verify customer
			The ETO concentration monitor is used to measure gas concentrations during processing. These gas levels are used to verify customer
			The ETO concentration monitor is used to measure gas concentrations during processing. These gas levels are used to verify customer
			The ETO concentration monitor is used to measure gas concentrations during processing. These gas levels are used to verify customer

[illegible]

[illegible]

[illegible]

[illegible]

Table 3. Control Characteristics for Sterilizer Chambers

Field #	E-1	E-51	E-52		
Data	Sterilizer unit ID	Is the sterilizer chamber vent (SCV) routed to any control device?	APCD 1 for sterilizer chamber vent (SCV)		
Instruction	This column will be auto-populated based on your entries in the previous fields	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column <u>If you select "Other (double click to specify)", be sure to type your entries between the parentheses "()"</u>	Enter the <u>average</u> air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)
Response	Chamber 1	Yes (fill out E-52 through E-69)	WS-1	Wet scrubber	300.00
	Chamber 2	Yes (fill out E-52 through E-69)	WS-1	Wet scrubber	300.00
	Chamber 3	Yes (fill out E-52 through E-69)	WS-1	Wet scrubber	300.00
	Chamber 4	Yes (fill out E-52 through E-69)	WS-1	Wet scrubber	300.00
	Chamber 5	Yes (fill out E-52 through E-69)	WS-1	Wet scrubber	300.00
	Chamber 6	Yes (fill out E-52 through E-69)	WS-1	Wet scrubber	300.00
	Chamber 7	Yes (fill out E-52 through E-69)	WS-1	Wet scrubber	300.00
	Chamber 8	Yes (fill out E-52 through E-69)	WS-1	Wet scrubber	300.00

[illegible]

	E-55	E-56	E-57	E-58	E-59	E-60
ny)	Material of duct work for sterilizer chamber vent (SCV)	Total length of duct work for sterilizer chamber vent (SCV)	Average thickness of duct work for sterilizer chamber vent (SCV)	Is the cross section of duct work for sterilizer chamber vent (SCV) circular or rectangular?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)
Enter the <u>average</u> air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)	Specify the material of duct work	Enter the <u>total</u> length of duct work (feet)	Enter the <u>average</u> thickness of duct work (inches)	Select from the dropdown menu in this column	Enter the <u>average</u> diameter of duct work (feet)	Enter the <u>average</u> cross-sectional height of duct work (feet)
	carbon steel and black iron	230.00	0.25	Circular (fill out E-59 & E-63 as appropriate)	0.33	
	carbon steel and black iron	210.00	0.25	Circular (fill out E-59 & E-63 as appropriate)	0.33	
	carbon steel and black iron	190.00	0.25	Circular (fill out E-59 & E-63 as appropriate)	0.33	
	carbon steel and black iron	170.00	0.25	Circular (fill out E-59 & E-63 as appropriate)	0.33	
	carbon steel and black iron	150.00	0.25	Circular (fill out E-59 & E-63 as appropriate)	0.33	
	carbon steel and black iron	200.00	0.25	Circular (fill out E-59 & E-63 as appropriate)	0.33	
	carbon steel and black iron	220.00	0.25	Circular (fill out E-59 & E-63 as appropriate)	0.33	
	carbon steel and black iron	240.00	0.25	Circular (fill out E-59 & E-63 as appropriate)	0.33	

[illegible][illegible]

[illegible][illegible]

[illegible][illegible]

[illegible][illegible]

[illegible]

E-83		E-83		E-83	
APCD 2 for chamber exhaust vent (CEV) (if any)		APCD 2 for chamber exhaust vent (CEV) (if any)		APCD 3 for chamber exhaust vent (CEV) (if any)	
Enter the <u>average</u> air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column <u>If you select "Other (double click to specify)", be sure to type your entries between the parentheses "()"</u>	Enter the <u>average</u> air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column <u>If you select "Other (double click to specify)", be sure to type your entries between the parentheses "()"</u>
1833.50					
1142.67					
1403.00					
1474.83					
1184.83					
1167.50					
1416.00					
1248.67					

[illegible][illegible]

[illegible][illegible]

[illegible][illegible]

[illegible][illegible]

[illegible][illegible]

E-109					E-110	
Stack parameter (for uncontrolled CEV only)					Stack coordinates (for uncontrolled CEV only)	
Enter the stack <u>height</u> (feet)	Enter the stack <u>diameter</u> (feet)	Enter the <u>temperature</u> at stack outlet (Fahrenheit)	Enter the <u>exhaust</u> <u>velocity</u> at stack outlet (feet/second)	Enter the <u>volumetric flow</u> <u>rate</u> at stack outlet (cubic feet/second)	Enter the latitude of stack. Specify to the <u>6th</u> decimal point	Enter the longitude of stack. Specify to the <u>6th</u> decimal point

	Chamber 9	Yes (fill out E-52 through E-69)	WS-1	Wet scrubber	300.00
	Chamber 10	Yes (fill out E-52 through E-69)	WS-1	Wet scrubber	300.00

Table 4. Control Characteristics for Sterilizer Chambers (continued)

Field #	E-1	E-111	E-112	E-113	
Data	Sterilizer unit ID	Is there a cover hood or vent over the sterilizer chamber door (e.g., hooded vent above the sterilizer chamber door)?	Is the cover hood or vent routed to any control device?	APCD 1 for cover hood or vent	
Instruction	This column will be auto-populated based on your entries in the previous fields	Select from the dropdown menu in this column	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column <u>If you select "Other (double click to specify)", be sure to type your entries between the parentheses "()"</u>
Response	Chamber 1	No (skip to E-133)			
	Chamber 2	No (skip to E-133)			
	Chamber 3	No (skip to E-133)			

[illegible]

E-114				E-115	E-116
APCD 2 for cover hood or vent (if any)				Material of duct work for cover hood or vent	Total length of duct work for cover hood or vent
Enter the <u>average</u> air flow routed from the cover hood or vent to this APCD (actual cubic feet per minute, acfm)	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column <u>If you select "Other (double click to specify)", be sure to type your entries between the parentheses "()"</u>	Enter the <u>average</u> air flow routed from the cover hood or vent to this APCD (actual cubic feet per minute, acfm)	Specify the material of duct work	Enter the <u>total</u> length of duct work (feet)

[illegible]

23	E-124		E-125		E-126	E-127
Duct work (duct work only)	Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional width of duct work (For rectangular duct work only)		Year in which duct work was installed	Expected lifetime of duct work
Enter the <u>minimum</u> diameter of duct work (feet)	Enter the <u>maximum</u> cross- sectional height of duct work (feet)	Enter the <u>minimum</u> cross-sectional height of duct work (feet)	Enter the <u>maximum</u> cross- sectional width of duct work (feet)	Enter the <u>minimum</u> cross-sectional width of duct work (feet)	Enter the calendar year	Enter the expected lifetime of duct work (years)

[illegible]

E-128		E-129		E-130		
Capital cost of duct work for cover hood or vent (estimated or actual)		Installation cost of duct work for cover hood or vent (estimated or actual)		Stack ID to which the cover hood or vent vents (for uncontrolled cover hood or vent only)	(for uncontrolled cover hood or vent only)	
Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height (feet)	Enter the stack diameter (feet)

[illegible]

E-131			E-132		E-133
Stack parameter (<u>controlled cover hood or vent only</u>)			Stack coordinates (<u>for uncontrolled cover hood or vent only</u>)		Is any SCV or CEV of the sterilizer unit routed to a vacuum pump?
Enter the <u>temperature</u> at stack outlet (Fahrenheit)	Enter the <u>exhaust velocity</u> at stack outlet (feet/second)	Enter the <u>volumetric flow rate</u> at stack outlet (cubic feet/second)	Enter the latitude of stack. Specify to the <u>6th</u> decimal point	Enter the longitude of stack. Specify to the <u>6th</u> decimal point	Select from the dropdown menu in this column <u>If your answer is</u> <u>"Yes" in any row</u> <u>below, fill out</u> <u>Table 5</u>
					Yes (fill out E-134 through E-143)
					Yes (fill out E-134 through E-143)
					Yes (fill out E-134 through E-143)

	Chamber 4	No (skip to E-133)			
	Chamber 5	No (skip to E-133)			
	Chamber 6	No (skip to E-133)			
	Chamber 7	No (skip to E-133)			
	Chamber 8	No (skip to E-133)			
	Chamber 9	No (skip to E-133)			
	Chamber 10	No (skip to E-133)			

Table 5. Vacuum Pumps

Field #	E-134	E-135	
Data	Unit ID of vacuum pump	Associated sterilizer unit ID(s) and vent(s)	
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each pump	Enter ID(s) of the sterilizer unit(s) associated with this vacuum pump. If more than one sterilizer unit is serviced by the vacuum pump, list all the sterilizer unit IDs separated by commas. Also specify which vents on the sterilizer unit are routed to the vacuum pump. For example: "SC-1 (SCV, CEV)"	Specify <u>make</u> of pump

[illegible]

E-136		E-137	E-138	E-139
Basic information of vacuum pump		Seal type of vacuum pump	Capacity of vacuum pump	Year in which the vacuum pump was installed
Specify <u>model</u> of pump	Specify <u>type</u> of pump. Select from the dropdown menu in this column If you select "Other (double click to specify)", be sure to type your entries between the parentheses "()"	Select from the dropdown menu in this column If you select "Other (double click to specify)", be sure to type your entries between the parentheses "()"	(cubic feet per minute, cfm)	Enter the calendar year

[illegible]

E-140	E-141		E-142		E-143
Expected lifetime of the vacuum pump	Capital cost of the vacuum pump		Annual cost of the vacuum pump		Handling and disposal of water from the vacuum pump
Enter the expected lifetime of the EtO concentration monitor (years)	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	If you selected "once-through" as the type of water handling, describe how the water is handled and disposed of

Response	Chamber 1 Vacuum Pump	Chamber 1 SCV	Travaini
	Chamber 2 Vacuum Pump	Chamber 2 SCV	Travaini
	Chamber 3 Vacuum Pump	Chamber 3 SCV	Travaini
	Chamber 4 Vacuum Pump	Chamber 4 SCV	Travaini
	Chamber 5 Vacuum Pump	Chamber 5 SCV	Travaini
	Chamber 6 Vacuum Pump	Chamber 6 SCV	Travaini
	Chamber 7 Vacuum Pump	Chamber 7 SCV	Travaini
	Chamber 8 Vacuum Pump	Chamber 8 SCV	Travaini
	Chamber 9 Vacuum Pump	Chamber 9 SCV	Travaini
	Chamber 10 Vacuum Pump	Chamber 10 SCV	Travaini

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F. Aeration

Table 1. Aeration that Occurs in Separate Unit (Aeration Room & Aeration Cell/Chamber)

Field #	F-1	F-2	F-3	F-4	F-5
Data	Aeration unit ID	Associated EIS release point ID	Type of aeration unit	Does the aeration unit use accelerated aeration?	Characteristics of accelerated aeration
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each aeration unit	Enter the EIS release point ID associated with the aeration unit, if any	Select from the dropdown menu in this column	Select from the dropdown menu in this column	Select from the dropdown menu in this column
Response	Degas 11		Aeration room	No (skip to F-6)	

Table 2. Aeration that Occurs within Sterilizer Chamber
If no data is auto-populated in Field E-1 of this table, skip to Table 3

Field #	E-1	F-43	F-44
Data	Sterilizer unit ID	Temperature	Relative humidity

F-45	F-46
Pressure	Length of time that products are being held in aeration room before being transferred

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

Instruction	This column will be auto-populated based on your entries in the previous fields	Enter the <u>average</u> temperature of aeration room when in operation (Fahrenheit)	Enter the <u>maximum</u> temperature of aeration room when in operation (Fahrenheit)	Enter the <u>minimum</u> temperature of aeration room when in operation (Fahrenheit)	Is a specific humidity needed for aeration? Select from the dropdown menu in this column	If yes, enter the specific humidity that is needed for aeration (percent)
Response						

Table 3. Movement of Sterilized Products through the Facility
Describe how sterilized product is moved from one area of the facility to another. For each product move through the facility provide, provide (1) product name, (2) date product is moved, (3) distance product is moved, and (4) note any areas where there is a hood to collect the EO

Field #	Data	Instruction	
F-47	From sterilizer chamber to aeration	Provide details on where the sterilized product is placed in	The product is remo
F-48	From aeration room/chamber to warehouse area	Provide details on where the sterilized and aerated product is placed after being removed from aeration chamber, length of time the sterilized and aerated product sits after being removed from aeration room, and distance the sterilized and aerated product is moved to warehouse area	After the aeration pr any open location in feet. Products sit on a deviation from cus
F-49	At warehouse area	Provide details on length of time sterilized and aerated	Shipping varies base

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G. Summary of Air Pollution Control Devices

Table 1. APCD Characteristics
If an APCD exhausts to more than one stack, provide the information requested in Fields G-5 through G-7 for each additional stack in Addition

Field #	G-1	G-2	G-3	G-4	
Data	APCD ID	Type of APCD	Associated EIS release point ID	Description	
Instruction	This column will be auto-populated based on your entries in the previous fields	This column will be auto-populated based on your entries in the previous fields	Enter the EIS release point ID associated with this APCD, if any	Specify the <u>manufacturer</u> of APCD	Specify the <u>model</u> of APCD
Response	WS-1	Wet scrubber		Croll Reynolds	82079/A10596
	SC-2	Dry-bed scrubber		Advanced Air Technologies	Safe Cell II
	SC-3	Dry-bed scrubber		Advanced Air Technologies	Safe Cell II
	SC-1	Dry-bed scrubber		Advanced Air Technologies	Safe Cell II

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

	G-18
the last 5 years (if any)	How does the APCD handle variability in flow rate and c parameters?
Provide a copy of each performance test performed in the last 5 years in its entirety for each APCD	Provide a brief description about how the APCD handles varia and other relevant parameters
Attach all requested documents in the "Attachments" tab	This APCD is designed/tested for worse case conditions
	This APCD is designed/tested for worse case conditions
	This APCD is designed/tested for worse case conditions
	This APCD is designed/tested for worse case conditions

[illegible]

Table 2. Emissions and CEMS

[illegible]

[illegible][illegible]

[illegible][illegible]

[illegible][illegible]

[illegible]

			Attach all requested documents in the "Attachments" tab

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H. Details of Air Pollution Control Devices

Table 1. Wet Scrubber & Glygen Absorber Unit

Field #	G-1	H-1
Data	APCD ID	Design and operation specifications
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the wet scrubber/glygen absorber unit
Response	WS-1	This is a wet scrubber system consisting of two packed towers and reactor tanks. As ethylene oxide enters this system it is drawn up through the tower packing and makes contact with a water-sulfuric acid scrubbing solution which absorbs

Table 2. Dry-bed Scrubber

Field #	G-1	H-12
Data	APCD ID	Design and operation specifications
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the dry-bed scrubber
Response	SC-2	Air is drawn out from the chamber exhaust vents and into the Safe Cell sytem. As
	SC-3	Air is drawn out from the chamber exhaust vents and into the Safe Cell sytem. As

Does any of the information you entered in this tab contain confidential business information (CBI)? Select from the options in Cell N2 on the right → If yes, be sure to shade the fields containing CBI in red, and follow the instructions specified in the Instructions Document

[illegible]

H-13	H-14	H-15	H-16	H-17
Type of media/sorbent used	Volume of media/sorbent	Year in which current media/sorbent was installed	Expected lifetime of media/sorbent	Can the media/sorbent be regenerated?
Specify the type of media/sorbent used for the dry-bed scrubber	Enter the volume of media/sorbent within the dry-bed scrubber (cubic feet)	Enter the calendar year in which the current media/sorbent was installed	Enter the expected lifetime of the media/sorbent used (years)	Select from the dropdown menu in this column
Safe Cell II Reactant Media	144.00	2019	0.25	No (skip to H-20)
Safe Cell II Reactant Media	48.00	2019	0.25	No (skip to H-20)

Yes

[illegible]

H-18 Media/sorbent regeneration				H-19 Average cost of media/sorbent regeneration
How frequently is the media/sorbent regenerated, if applicable?	What method is used to regenerate the media/sorbent, if applicable?	How many times is the media/sorbent regenerated prior to disposal, if applicable?	To what removal efficiency is the media/sorbent restored after regeneration? (percent)	Enter the dollar amount in this column

[illegible]

19	H-20	H-21		H-22	
media/sorbent ion event	Sorbent disposal	Annual cost of sorbent disposal		Is the media/sorbent activity monitored way?	
Specify the dollar year in this column	Specify how sorbent is disposed (e.g., hazardous waste landfill, MSW landfill, etc.)	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	If yes, provide a brief column
	MSW landfill			Yes	We monitor the amount
	MSW landfill			Yes	We monitor the amount

[illegible]

	H-23	H-24
Is the media/sorbent change out done based on manufacturer suggestion?		Process/APCD monitoring plan for dry-bed scrubber
Provide a brief description of the process/APCD monitoring plan for the dry-bed scrubber. Specify if measurements of the gas stream or sorbent are taken and if so, how often.	Select from the dropdown menu in this column. If you select "No", be sure to enter a brief explanation between the parentheses "()"	Provide a brief description of the process/APCD monitoring plan for the dry-bed scrubber. Specify if measurements of the gas stream or sorbent are taken and if so, how often.
Amount of ethylene	Yes	This system was recently installed and defined monitoring instruments
Amount of ethylene	Yes	This system was recently installed and defined monitoring instruments

[illegible]

	H-25				
scrubber	Parameter 1 monitored for dry-bed scrubber				
Plan for the dry-bed material are part	<u>Name of Parameter 1</u>	<u>Set value of Parameter 1</u>	<u>Unit of Parameter 1</u>	<u>Monitoring frequency of Parameter 1</u>	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 1
Instructions have not					
Instructions have not					

H-10					H-
Parameter 4 monitored for wet scrubber/glygen absorber unit (if any)					Monitoring re scrubber/glyg unit from the ve
Name of Parameter 4	Set value of Parameter 4	Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all mor records from th calendar year
pH	2.00	maximum pH level	weekly	A quantity of the solution in the reactor tanks is pumped to a storage tank. Water is added to the reactor tank to	Attach all documer "Attachm

H-26					
Parameter 2 monitored for dry-bed scrubber (if any)					
Name of Parameter 2	Set value of Parameter 2	Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2	Name of Parameter 3

11
cords for wet gen absorber last calendar ar nitoring ie last
requested its in the ents" tab

H-27						
Parameter 3 monitored for dry-bed scrubber (if any)				Parameter 4 monitored		
Set value of Parameter 3	Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4	Set value of Parameter 4	Unit of Parameter 4

H-28		H-29
for dry-bed scrubber (if any)		Monitoring records for dry-bed scrubber from the last calendar year
Monitoring frequency of Parameter 4	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year

	SC-1	Air is drawn out from the aeration rooms and into the Safe Cell sytem. As air enters this system it passes through the Safe Cell II Reactant Media which is housed in mutliple Safe Cell DR-490 units. The ethylene oxide is irreversibly reacted on the surface of the reactant media and clean air is discharged from the unit. The Safe Cell system at Midwest Sterilization Corporation Laredo consits of 26 individual Safe Cell DR-490 units.

Table 3. Catalytic Oxidizer & Balancer/Abator

Field #	G-1	H-30
Data	APCD ID	Design and operation specifications
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the catalytic oxidizer or balancer/abator
Response		

Safe Cell II Reactant Media	624.00	2019	0.25	No (skip to H-20)

H-31	H-32	H-33	H-34	H-35
Type of catalyst	Volume of catalyst	Year in which current catalyst was installed	Expected lifetime of catalyst	Operating temperature of catalyst bed
Specify the type of catalyst used in catalytic oxidizer	(cubic feet)	Enter the calendar year in which the current catalyst was installed	Enter the expected lifetime of the catalyst used (years)	Enter the operating temperature of catalyst bed (Fahrenheit)

[illegible][illegible]

[illegible][illegible]

[illegible][illegible]

[illegible][illegible]

[illegible][illegible]

		Attach all requested documents in the "Attachments" tab

H-48			H-49
monitored for catalytic oxidizer & balancer/abator (if any)			Monitoring records for catalytic oxidizer & balancer/abator from the last calendar year
Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year
			Attach all requested documents in the "Attachments" tab

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Table 4. Thermal Oxidizer

Field #	G-1	H-50
Data	APCD ID	Design and operation specifications
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the thermal oxidizer
Response		

Table 5. Other APCDs

Field #	G-1	H-61
Data	APCD ID	Design and operation specifications
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the APCD
Response		

[illegible]ED 005957 00000085-00230

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H-55		H-	
Process/APCD monitoring plan for thermal oxidizer		Parameter 1 monitored	
Provide a brief description of the process/APCD monitoring plan for the thermal oxidizer. Specify if measurements of the gas stream are part of these plans	<u>Name of Parameter</u> 1	<u>Set value of</u> Parameter 1	<u>Unit of Parameter</u> 1

H-63			H-		
Parameter 1 monitored for APCD			Parameter 2 monitored		
<u>Unit of Parameter</u> 1	<u>Monitoring frequency of</u> Parameter 1	<u>Explain any corrective actions taken</u> for readings outside the limit(s) for Parameter 1	<u>Name of Parameter</u> 2	<u>Set value of</u> Parameter 2	<u>Unit of Parameter</u> 2

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[illegible]

[illegible]ED_005957_00000085-00234

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H-60
Monitoring records for thermal oxidizer from the last calendar year
Provide all monitoring records from the last calendar year
Attach all requested documents in the "Attachments" tab

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I. EtO Monitoring

Table 1. Personal Monitoring (Badges) for EtO

List all personal monitoring events during the last 5 years

[illegible]

Table 2. Room Area Monitoring for EtO

Field #	B-1	I-9	
Data	Room area ID for all rooms and areas where EtO is used or emitted	Description of room area monitoring	EtO concentration
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the monitoring procedure for each room	Enter the <u>average</u> EtO concentration (ppmv)

[illegible]

I-10		I-11	I-12	I-13
of room area where EtO is used or emitted		How many measurement points are there within the room area?	What is the frequency of monitoring at each point within the room area?	Instrument used to monitor the room area
Enter the <u>maximum</u> EtO concentration (ppmv)	Enter the <u>minimum</u> EtO concentration (ppmv)	Enter the amount of measurement points within the room area	Specify the frequency of monitoring at each point within the room area	Specify the instrument used to monitor the room area

I-7			I-8
Instrument 1			Instrument 2 (if any)
Specify the instrument used during each personal monitoring event	Enter the <u>value</u> of detection level of instrument	Specify the <u>unit</u> of detection level of instrument	Specify the instrument used during each personal monitoring event
Ethylene oxide is collected on a	0.01	ppm	
Ethylene oxide is collected on a	0.01	ppm	
Ethylene oxide is collected on a	0.01	ppm	
Ethylene oxide is collected on a	0.01	ppm	
Ethylene oxide is collected on a	0.01	ppm	
Ethylene oxide is collected on a	0.01	ppm	
Ethylene oxide is collected on a	0.01	ppm	
Ethylene oxide is collected on a	0.01	ppm	
Ethylene oxide is collected on a	0.01	ppm	
Ethylene oxide is collected on a	0.01	ppm	

		I-14		
ent 1		Instrument 2 (if any)		
Enter the <u>value</u> of detection level of instrument	Specify the <u>unit</u> of detection level of instrument	Specify the instrument used to monitor the room area	Enter the <u>value</u> of detection level of instrument	Specify the <u>unit</u> of detection level of instrument

Response	EO Room	Gas chromatograph and LEL monitoring	
	Chamber 1	Gas chromatograph and LEL monitoring	
	Chamber 2	Gas chromatograph and LEL monitoring	
	Chamber 3	Gas chromatograph and LEL monitoring	
	Chamber 4	Gas chromatograph and LEL monitoring	
	Chamber 5	Gas chromatograph and LEL monitoring	
	Chamber 6	Gas chromatograph and LEL monitoring	
	Chamber 7	Gas chromatograph and LEL monitoring	
	Chamber 8	Gas chromatograph and LEL monitoring	
	Chamber 9	Gas chromatograph and LEL monitoring	
	Chamber 10	Gas chromatograph and LEL monitoring	
	Vacuum Pump Room	Gas chromatograph and LEL monitoring	
	Warehouse	Gas chromatograph and LEL monitoring	
	Emissions Room	Gas chromatograph and LEL monitoring	
	Safe Cell		

Table 3. Other Monitoring for EtO

Field #	Data	
I-16	Describe any other types of EtO monitoring that have been	
I-17	Describe any dispersion modeling efforts conducted by the facility	
I-18	Provide the records for any type of monitoring or modeling	Attach all

		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
				Chromatograph System
		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
				Chromatograph System
		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
				Chromatograph System
		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
				Chromatograph System
		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
				Chromatograph System
		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
				Chromatograph System
		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
				Chromatograph System
		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
				Chromatograph System
		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
				Chromatograph System
		1	every 45 minutes	Mocon-Baseline 8900 Series Gas
				Chromatograph System

Response
requested documents in the "Attachments" tab

0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
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0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit
0.04	ppm	GFG MWG 0238 Ex	0%	percent of lower explosive limit

Attach all
requested
documents in the
"Attachments" tab

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J. Wastewater

Field #	J-1	J-2		J-3	J-4	
Data	Daily average wastewater flow rate for EtO commercial sterilization activities at the facility	Annual EtO emissions from wastewater at facility for the last 5 years		Average EtO concentration in wastewater when it leaves the vacuum pump or liquid-gas separator	Average EtO concentration in wastewater when collected in a holding tank or basin	Wastewater disposal
Instruction	(gallons/day)	Enter calendar year in this column	Enter the value of annual EtO emissions in this column (pounds)	(ppmv)	(ppmv)	Briefly specify how EtO commercial sterilization is performed
Response	0.14					

K. Unique Cycles and EtO Reduction

Enter data for each individual category, respectively

If the facility does not plan to re-validate cycles in an effort to reduce EtO use, responses are not required for Fields K-2 through K-4 and K-7

Field #	K-1	K-2	K-3	K-4	
Data	How many unique cycles are run at this facility?	How many unique cycles have been re-validated thus far?	How many unique cycles does the facility still have left to re-validate	How long will it take to complete re-validation of these cycles?	
Instruction	Enter the amount of unique cycles	Enter the amount of unique cycles	Enter the amount of unique cycles	Enter the value in this column	Specify the unit in this column
Response for all the products in total	7	7	7	3.00	years
Response for 510(k) products (Class I and Class II devices)					
Response for Pre-Market Approval (PMA) products (Class III devices)					

Does any of the information you entered in this tab contain confidential business information (CBI)? Select from the options in Cell N2 on the right →
If yes, be sure to *shade the fields containing CBI in red*, and follow the instructions specified in the Instructions Document

Yes

J-5	J-6		J-7	J-8
Disposal or treatment for EtO commercial sterilization activities	Annual average cost of wastewater disposal or treatment for EtO commercial sterilization activities		Are there any other processes within the facility that generate EtO-laden wastewater?	Other processes generating EtO-laden wastewater within the facility
Wastewater is disposed of or treated for commercial sterilization activities	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	List all other processes generating EtO-laden wastewater within the facility. Enter one process per line.
			No (skip to J-12)	

through K-13

K-5	K-6	K-7	K-8
Cost of validating unique cycles	What is the current average EtO dose among the products?	What is the target average EtO dose?	What is the anticipated change in number of cycles upon completion of validation?
Provide information on the cost to validate a sterilization cycle, including: (1) hours of time for R&D engineers, operators, technicians, etc. to complete the sterilization cycle runs, compile the reports and file with the FDA; (2) costs for laboratory analyses; and (3) information on the length of time from start to finish (weeks) required to complete validation for a sterilization cycle	(mg/L)	(mg/L)	(percent)
Revalidating sterilization cycles will be largely dependent on the customer. Different types of medical products require different amounts of studies, types of laboratory analysis, various regulatory lead times, etc. The hours of			

	J-9	J-10	J-11	
wastewater within	Daily average wastewater flow rate for each process other than EtO commercial sterilization	Wastewater disposal or treatment for each process other than EtO commercial sterilization	Annual cost of wastewater disposal or treatment for each process other than EtO commercial sterilization	
den wastewater each row	(gallons/day)	For each process, briefly specify how wastewater is disposed of or treated	Enter the dollar amount in this column	Specify the dollar year in this column

8	K-9	K-10	K-11
ted average percent of nitrogen washes the re-validations?	What is the anticipated average percent change in <u>number of air washes</u> upon completion of the re-validations?	What is the anticipated average percent change in <u>time spent on gas washing</u> upon completion of the re-validations?	What is the anticipated average percent change in <u>dwel period time</u> upon completion of the re-validations?
	(percent)	(percent)	(percent)

J-12
Annual average wastewater flow for <u>all operations</u> at the facility (includes both EtO commercial sterilization and other activities)
(gallons/year)
51.10

K-12	K-13	
What is the anticipated average percent change in <u>aeration time</u> upon completion of the re-validations?	What are the anticipated annual cost savings from reduced EtO use?	
(percent)	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column

L. Other Questions regarding EtO Commercial Sterilization

Field #	Data	
L-1	How is EtO handled during malfunction events of process equipment (vented,	Chambers are under vacuum. Vacuum p
L-2	How is EtO handled during malfunction events of APCD (vented, held within	Held within chamber.
L-3	Provide documentation of any studies done on quantifying EtO residuals in	Attach all
L-4	Are there generators on site to keep facility running in the event of a power	Generator is only able to power emerge
L-5	Provide percent emission reduction, associated costs, and description of	MSC has continuously worked to revalid
L-6	Is the facility operating at full capacity or can current capacity increase to	We are operating at full capacity.

Response
pumps will activate prior to reaching atmospheric pressure and the gas will be
requested documents in the "Attachments" tab
ncy lighting, telephones, biological indicator storage room, and incubator.
ate sterilization cycles to reduce the amount of ethylene oxide remaining in

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M. Additional Information

If you need extra space to provide any additional information within this survey, use this section below. For each entry, spe

Tab	Field #	
Facility Details	A43	This is the electric and gas costs for the facility summed over the last 5 years divid
Facility Details	A44	This is the sterilization sales for the facility summed over the last 5 years divided b
EtO&EG Storage	C2	Amount that can be stored at once
Sterilizer Chambers	E10	These are all negative pressure (the pressure below atmospheric pressure), howev
Sterilizer Chambers	E75	The control software we use will not allow the cycle to finish without first going th
APCD Summary	G4	This system was added onto going from once tower to two towers in parallel
Room Area	B12 to B20	While air is not forced into any of the NDOs, the entire facility is kept under a vacu
Room Area	B59	These are all square exhaust openings, with the listed diameter being the length o
Sterilizer Chambers	E52	There is only one wet scrubbing system currently at this facility, however, this syst
APCD Summary	G20	this monitoring has not been implemented yet, however will be soon
Aeration	All	We are using the supplemental spreadsheet for the aeration room, however, we h
Miscellaneous	K-2 through K-3	Midwest Sterilization has continuously worked to revalidate cycle for lower ethyle
Sterilizer Chambers	E96	Back vents were always in place. They were hooked up to an air pollution control c
Room Area	B8	This is not something that is monitored and we do not have sufficient equipment t
Room Area	B12 through B21	Air is not forced through any of the natural draft openings with a fan, however, th
Room Area	B7	These are all estimates bases on the available information
EtO&EG Storage	D7 and D8	These are estimates of current pricing for these tanks, these specific tanks were in
Sterilizer Chambers	E14	This is not a direct measurement, however, is a calculated estimate
Sterilizer Chambers	E15	We do not rack this data or have an appropriate method to measure/calculate an
Sterilizer Chambers	E17	This is not a direct measurement, however, is a calculated estimate
Sterilizer Chambers	E18	We do not track this data or have an appropriate method to measure/calculate an
Sterilizer Chambers	E19	We do not track this data or have an appropriate method to measure/calculate an
Sterilizer Chambers	E20	We do not track this data or have an appropriate method to measure/calculate an
Sterilizer Chambers	E25	These are all estimates bases on the available information
Sterilizer Chambers	E52	We do not monitor these airflow amounts so this is a calculated estimate from the
Sterilizer Chambers	E67	These are all estimates bases on the available information
Sterilizer Chambers	E68	These are all estimates bases on the available information
Sterilizer Chambers	E69	These are all estimates bases on the available information
Sterilizer Chambers	E97	These are all estimates bases on the available information
Sterilizer Chambers	E98	All sterilization chambers were completed at once, this is an estimate of the cost p

Does any of the information you entered in this tab contain confidential business information (CBI)? Select from the options in Cell N2 on the right →
If yes, be sure to shade the fields containing CBI in red, and follow the instructions specified in the Instructions Document

No

Specify the tab name and field number to which your answer refers

Response
ed by 5. The dollar year amounts are 2015 to 2019
y 5. The dollar year amounts are 2015 to 2019
ver, this spreadsheet will not let you put in a negative sign
rough all of the cycle's washes if ethylene oxide has been introduced into the chamber.
um so the vacuum pressure of the facility will pull air through all of these openings towards the various exhaust fans
f the sides
em consists of two packed towers. Each of these towers has its own identifier as listed in our operating permit
ad to fill this section out so that the APCD IDs would auto populate on the APCD summary and the APCD Details Pages
ne oxide emissions, however, we are always working to continuously revalidate them and reduce emissions even further
device last year
to properly record it
e facility is kept under a slight vacuum so air will be constantly pulled through these openings
stalled many years ago and records for pricing are not available
accurate amount
y amount that is accurate
y amount that is accurate
y amount that is accurate
available information
er sterilization chamber

Sterilizer Chambers	E99	All sterilization chambers were completed at once, this is an estimate of the cost p
Aeration	F26	All of the aeration rooms are routed to the same control device and share sections
Aeration	F37	These are all estimates bases on the available information
Aeration	F38	These are all estimates bases on the available information
Aeration	F39	These are all estimates bases on the available information
APCD Summary	G9	These are all estimates bases on the available information
APCD Summary	G19	WS-1 is not continuously monitored for ethylene oxide emissions rates
Miscellaneous	J2	This information is kept by the wastewater treatment company
Miscellaneous	J3	This information is kept by the wastewater treatment company
Miscellaneous	J4	This information is kept by the wastewater treatment company

per sterilization chamber
s of the duct work. This is the total amount of duct work divided by the amount of aeration rooms. Summing this column would

Ethylene Oxide (EtO) Commercial Sterilization

CAA Section 114 Survey

[Click here to return to Introduction tab](#)

[Click here to visit Terms tab](#)

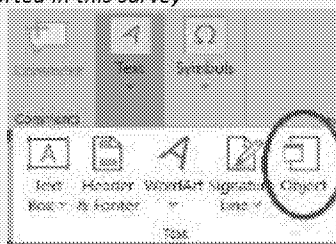
[Click here to visit Additional Info tab](#)

N. Attachments

Instructions: *Attach all documents and records requested throughout this survey on this page.*
Corresponding field numbers and data descriptions are summarized in the table below.
Ensure that any IDs referenced are consistent with data reported in this survey

Steps to attach files to this Excel spreadsheet

- (1) Click on the field to attach files;
 - (2) Go to the Insert tab → Text, click Object;
 - (3) In the Object dialog box, click the Create from File tab;
 - (4) Click Browse, and select the file you want to insert;
 - (5) Select the Display as Icon check box, then click OK.
- Repeat the above steps to attach any additional files*



Field #	Data	Instruction	
A-21	Facility diagrams	Provide diagrams of your facility indicating all rooms,	
A-22	Process flow diagrams	Provide process flow diagrams of the EtO processes at your	
A-23	Most Recent Air Permit(s)	Provide the most recent air permit(s) approved for your	
A-24	Application Documents for the Most	Provide the application documents for the most recent air	
A-25	Startup, shutdown and malfunction	Provide the startup, shutdown and malfunction (SSM) plan	
A-42	Documentation for annual emissions	Provide calculations and supporting documentation for all	
G-17	Performance test performed in the last	Provide a copy of each performance test performed in the	
G-28	Engineering emission test performed in	Provide a copy of each engineering emission test performed	
H-11	Monitoring records for wet scrubber	Provide all monitoring records from the last calendar year	
H-29	Monitoring records for dry-bed	Provide all monitoring records from the last calendar year	
H-49	Monitoring records for catalytic oxidizer	Provide all monitoring records from the last calendar year	
H-52	Operating temperature records for	Provide the operating temperature records for thermal	
H-60	Monitoring records for thermal oxidizer	Provide all monitoring records from the last calendar year	
H-67	Monitoring records for APCD from the	Provide all monitoring records from the last calendar year	
I-15	Action levels and SOPs for room area	Provide documents specifying action levels and SOPs for	
I-18	Provide the records for any type of		
L-3	Provide documentation of any studies		
N-1	Provide any process and		

ATTENTION - If any of the documents and records you choose to submit contains confidential business information (CBI), be sure to shade the corresponding fields in red and follow the instructions specified in the Instructions Document on how to handle and transport CBI

[illegible]

Ethylene Oxide (EtO) Commercial Sterilization CAA Section 114 Survey

[Click here to return to Introduction tab](#)

Certification by Reporter

Complete the fields below for the person who completes the survey and who is available for follow-up questions, if any, on the information provided in this survey

Name	Eric Sisk
Title	Director of Operations
Organization	Midwest Sterilization Corp
Email	erics@midweststerilization.com
Phone	573.243.8456
Fax	573.243.3799
General comments	



I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.

Eric Sisk

Signature

2/6/2020

Date

Certification by

Please complete the
this survey (may be i

Name	
Title	
Organization	
Email	
Phone	
Fax	
General comments	



Certification by Professional Engineer

Complete the fields below for the professional engineer (PE) who certifies the information provided in this survey

Name	
Title	
Organization	
Email	
Phone	
Fax	
General comments	



I certify that the statements and information are to the best of my knowledge

Certification by

Complete the fields i
provided in this surv

Name	
Title	
Organization	
Email	
Phone	
Fax	
General comments	



Facility Personnel

fields below for the facility personnel who certifies the information provided in the owner or legal operator of the facility)

Karen E. Fitzpatrick
President
Midwest Sterilization Corp
karenf@midweststerilization.com
573.243.8456
573.243.3799

I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.

Karen E. Fitzpatrick

Signature

2/6/2020

Date

Certified Industrial Hygienist

below for the certified industrial hygienist (CIH) who certifies the information

I certify that the statements and information are to the best of my knowledge

Exhibit

and belief true, accurate, and complete.

Signature

Date

Exhibit

and belief true, accurate, and complete.

Signature

Date

A-5 & A-16	A-9	B-2
AK	≤ 100	EtO storage
AZ	101-250	Preconditioning
AR	251-500	EtO dispensing room
CA	> 500	Sterilizer room area
CO		Aeration room area
CT	A-10	Aeration room
DE	Operating	Shipping or warehouse
DC	Seasonal/partial year	APCD room
FL	Temporarily closed	Other (double click to specify)
GA	Permanently closed	
HI		B-22
ID	A-12	Yes
IL	Yes	No (skip to B-38)
IN	No (skip to A-13)	
IA		B-23
KS	A-19	Valve - gas
KY	Yes	Valve - liquid
LA	No	Connector
ME		Flange - gas
MD	A-20	Flange - liquid
MA	≤ 250	Pump seal - liquid
MI	251-500	Pressure relief device
MN	501-750	Meter - gas
MS	751-1000	Meter - liquid
MO	1001-1250	Line
MT	> 1250	Other (double click to specify)
NE		
NV		B-36
NH		Yes
NJ		No (skip to B-37)
NM		
NY		B-37
NC		Yes
ND		No (skip to B-38)
OH		
OK		B-38
OR		APCD (fill out B-39 through B-56)
PA		Cascading (fill out B-57)
RI		Atmosphere (fill out B-58 through B-60)
SC		Other handling (fill out B-61)
SD		
TN		B-45
TX		Circular (fill out B-46 & B-50 as appropriate)
UT		Rectangular (fill out B-47/48 & B-51/52 as appropriate)
VT		
VA		B-49
WA		Yes (skip to B-53)
WV		No (fill out respective fields)
WI		
WY		
AS		
GU		
MH		
FM		
MP		
PW		
PR		
VI		

NDO Type	C-3	CBI
Door	Yes	Yes
Window	No (skip to C-5)	No
Other (double click to specify)		
NDO Orientation	C-7	
Vertical	Yes	
Horizontal	No (skip to C-9)	
Combined		
Air forced out of NDO	C-11	
Yes	Yes	
No (skip the next column)	No	
	D-10	
	Yes (fill out D-11 through D-27)	
	No (fill out D-28 through D-30)	
	D-16	
	Circular (fill out D-17 & D-21 as appropriate)	
	Rectangular (fill out D-18/19 & D-22/23 as appropriate)	
	D-20	
	Yes (skip to D-24)	
	No (fill out respective fields)	

E-3/E-4/E-5/E-11

Yes

No

APCD

Wet scrubber

Glygen absorber unit

Dry-bed scrubber

E-21

Yes

No (skip to E-29)

Catalytic oxidizer

Thermal oxidizer

Balancer/abator

Other (double click to specify)

E-29

Yes

No (skip to E-37)

E-38

ppm

% LEL

E-40

Yes

No (skip to E-51)

E-41

Yes

No (skip to E-45)

E-51

Yes (fill out E-52 through E-69)

No (fill out E-70 through E-72)

E-58

Circular (fill out E-59 & E-63 as appropriate)

Rectangular (fill out E-60/61 & E-64/65 as appropriate)

E-62

Yes (skip to E-66)

No (fill out respective fields)

E-73

Yes

No (skip to E-111)

E-74

Yes

No (skip to E-75)

E-75

Yes

No (skip to E-81)

E-81

Yes (fill out E-82 through E-107)

No (fill out E-108 through E-110)

E-88

Circular (fill out E-89 & E-93 as appropriate)

Rectangular (fill out E-90/91 & E-94/95 as appropriate)

E-92

Yes (skip to E-96)

No (fill out respective fields)

F-3 Aeration room Aeration cell/chamber	G-16 Yes No	H-17 Yes No (skip to H-20)	J-7 Yes No (skip to J-12)
--	--------------------------	---	--

F-4 Yes No (skip to F-6)	G-20 Yes No (skip to G-28)	H-22 Yes No (skip to H-23)
---------------------------------------	---	---

F-5 Pull vacuum Multiple inlet and outlet vents on cell Other (double click to specify)	H-23 Yes No (double click to specify)
---	--

F-8 Yes No (skip to F-9)	H-39 Yes No (skip to H-42)
---------------------------------------	---

F-14
Yes
No (skip to F-22)

F-22
Yes (fill out F-23 through F-39)
No (fill out F-40 through F-42)

F-28
Circular (fill out F-29 & F-33 as appropriate)
Rectangular (fill out F-30/31 & F-34/35 as appropriate)

F-32
Yes (skip to F-36)
No (fill out respective fields)

F-44
Yes
No (skip to F-45)

[illegible]

G-1 no dup no blank	APCD Type	APCD Details (AM)	B-1	B-1 with no 0	Additional Info
WS-1	Wet scrubber	WS-1	EO Room	EO Room	Facility Details
SC-2	Dry-bed scrubber	SC-2	Chamber 1	Chamber 1	Room Area
SC-3	Dry-bed scrubber	SC-3	Chamber 2	Chamber 2	EtO&EG Storage
SC-1	Dry-bed scrubber	SC-1	Chamber 3	Chamber 3	Sterilizer Chambers
			Chamber 4	Chamber 4	Aeration
			Chamber 5	Chamber 5	APCD Summary
			Chamber 6	Chamber 6	APCD Details
			Chamber 7	Chamber 7	EtO Monitoring
			Chamber 8	Chamber 8	Miscellaneous
			Chamber 9	Chamber 9	Attachments
			Chamber 10	Chamber 10	Certification
			Vacuum Pump Room	Vacuum Pump Room	
			Warehouse	Warehouse	
			Emissions Room	Emissions Room	
			Safe Cell	Safe Cell	
			0		
			0		
			0		
			0		
			0		

E-100

Yes (fill out E-107)

No

E-101

Yes

No (skip to E-111)

E-111

Yes

No (skip to E-133)

E-112

Yes (fill out E-113 through E-129)

No (fill out E-130 through E-132)

E-118

Circular (fill out E-119 & E-123 as appropriate)

Rectangular (fill out E-120/121 & E-124/125 as appropriate)

E-122

Yes (skip to E-126)

No (fill out respective fields)

E-133

Yes (fill out E-134 through E-143)

No (skip to F-1)

E-136

Once-through

Recirculating

Other (double click to specify)

E-137

Wet seal with water

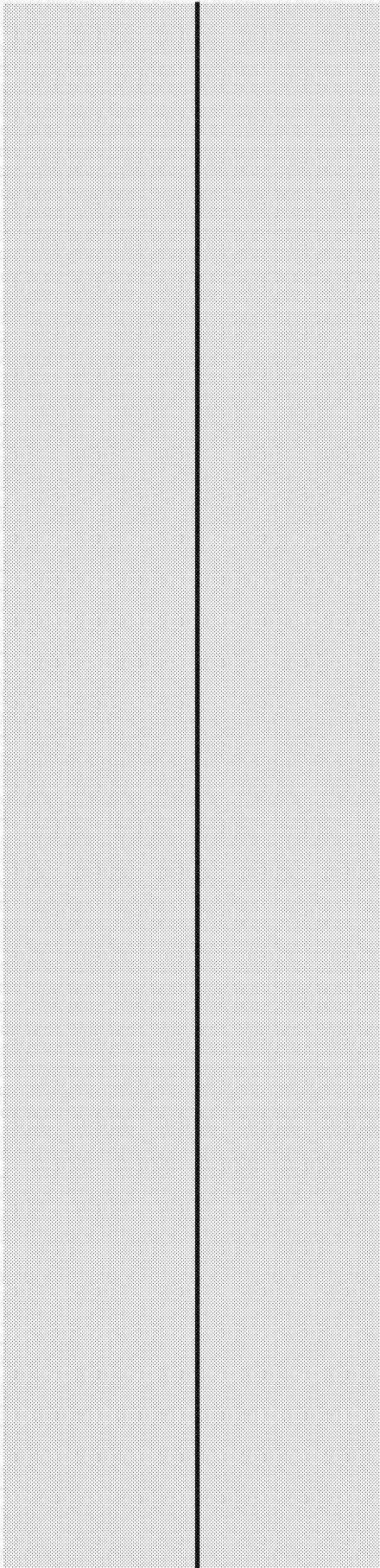
Wet seal with oil

Wet seal with other fluid

Dry seal

Other (double click to specify)

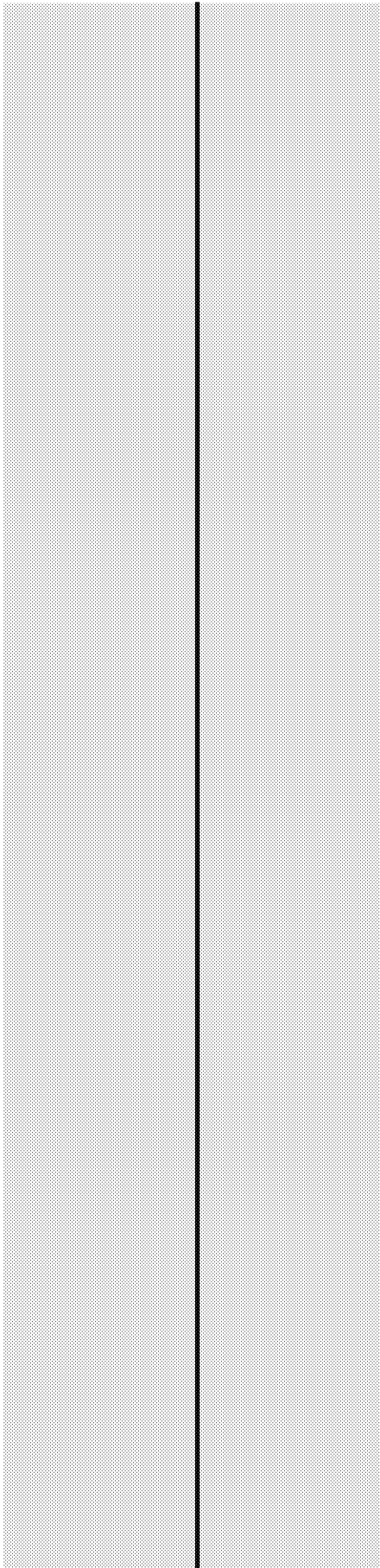
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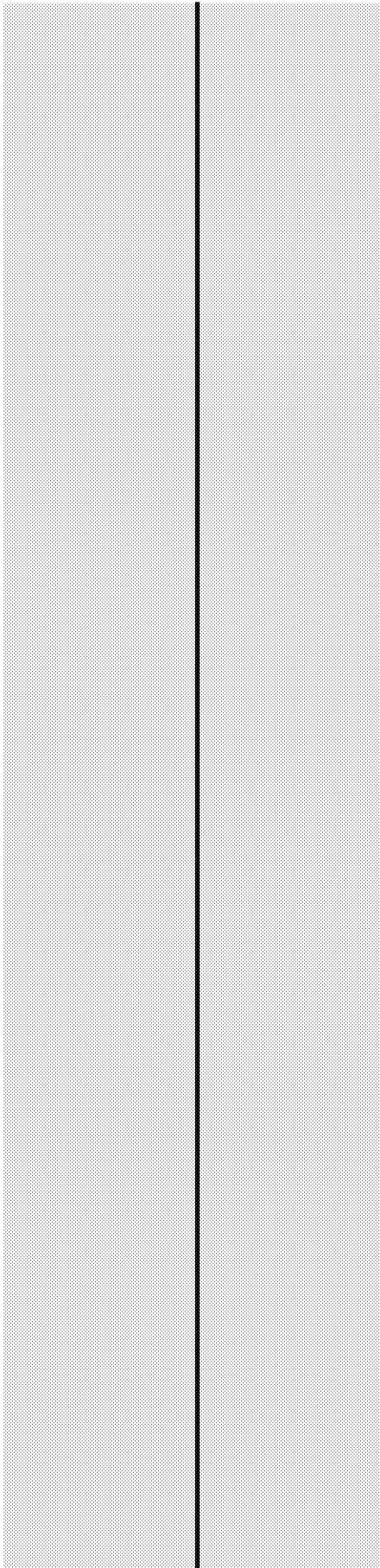
[illegible]

E-53

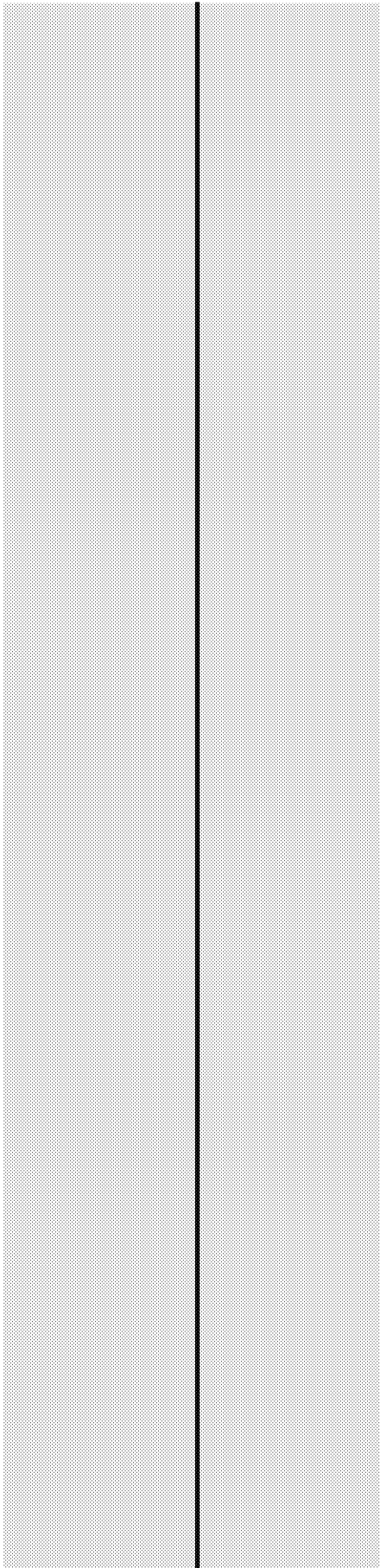
E-54



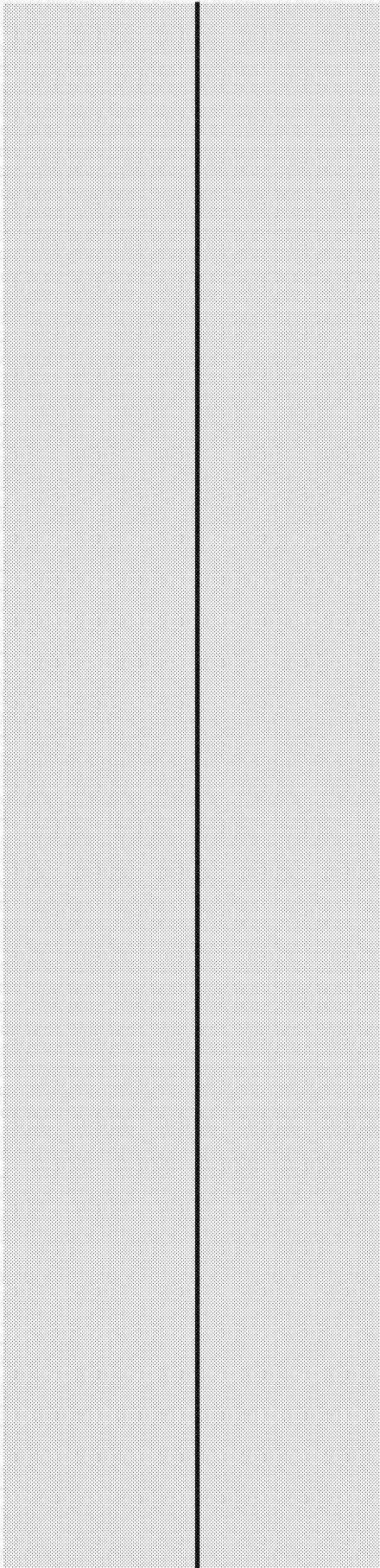
[illegible]



E-113



[illegible]



[illegible]

